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EXAMINER

HUPCZEY, JR, RONALD JAMES

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTOPHER J. DANEK, GARY S. KAPLAN,
WILLIAM J. WIZEMAN, and MICHAEL D. LAUFER

Appeal 2013-006461¹
Application 11/617,512²
Technology Center 3700

Before MICHAEL C. ASTORINO, BRUCE T. WIEDER, and
MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEYERS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 11, 12, and 29–38. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ Our decision references Appellants' Appeal Brief ("Appeal Br.," filed October 26, 2012) and Reply Brief ("Reply Br.," filed April 12, 2013), and the Examiner's Answer ("Ans.," mailed February 13, 2013) and Final Office Action ("Final Act.," mailed November 10, 2011).

² Appellants identify Asthmatx, Inc., as the real party in interest (Appeal Br. 3).

CLAIMED INVENTION

Appellants' invention relates "a new treatment for asthma" which "comprises the application of energy to the airway smooth muscle tissue" (Spec. ¶ 4).

Claim 11, reproduced below with added bracketed notations, is illustrative of the subject matter on appeal:

11. A method, comprising:

[a] delivering a therapeutic energy to tissue at a first treatment site of an airway of a lung via an energy delivery device so as to treat asthma;

[b] filtering tissue images of a portion of the airway of the lung proximate the first treatment site from a bronchoscopic visualization system, wherein the tissue images show both tissue at the first treatment site that has received the therapeutic energy from the energy delivery device and tissue apart from the first treatment site that has not received the therapeutic energy from the energy delivery device;

[c] determining a second treatment site along the portion of the airway of the lung based on the filtered tissue images; and

[d] delivering the therapeutic energy to the second treatment site via the energy delivery device.

Appeal Br. (Claims. App.).

REJECTIONS

Claim 33 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 11, 12, and 29–38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 11, 12, 29, and 32–38 are rejected under 35 U.S.C. § 103(a) as unpatentable over Laufer (US 5,972,026, iss. Oct. 26, 1999) and McGee (US 5,722,403, iss. Mar. 3, 1998).

Claims 30 and 31 are rejected under 35 U.S.C. § 103(a) as unpatentable over Laufer, McGee, and *Changes in Birefringence as Markers of Thermal Damage in Tissues* to Thomsen et al. (hereinafter “Thomsen”) and “Birefringence characterization of biological tissue by use of optical coherence tomography” to Everett et al. (hereinafter “Everett”) (*see* Final Act. 7).

ANALYSIS

Written description

In rejecting dependent claim 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, the Examiner finds that there is no written description support in the Specification to support “the delivery of the therapeutic and non-therapeutic energy to be occurring at the same time,” as required by claim 33 (Final Act. 2). The Examiner maintains the rejection is proper because “at no time has the Examiner found the placement of the source **242** on or in close proximity to the energy transfer element **108** to necessarily or inherently require that the therapeutic and non-therapeutic energies be delivered simultaneously” (Ans. 10).

Appellants argue that the rejection “is improper because the Examiner has not met his burden of showing that a person skilled in the art would not recognize disclosure of claim 33 in Appellant’s disclosure” (Appeal Br. 9). More particularly, Appellants argue that “[p]aragraphs 100 through 108 in Appellant’s specification include disclosure of an illumination source” (*id.*) which “may be configured to provide additional light when the device is

used without a scope or to supplement the illumination of the scope” (*id.* at 10 (citing Spec. ¶ 100)).

Whether a specification complies with the written description requirement of 35 U.S.C. § 112, first paragraph, is a question of fact and is assessed on a case-by-case basis. *See, e.g., Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)). The disclosure, as originally filed, need not literally describe the claimed subject matter (i.e., using the same terms or *in haec verba*) in order to satisfy the written description requirement. But the Specification must convey with reasonable clarity to those skilled in the art that, as of the filing date, Appellants were in possession of the claimed invention (*see id.*).

Here, we agree with Appellants that one of ordinary skill in the art would understand from the Specification, including at least paragraphs 100 through 108, that Appellants were in possession of the claimed subject matter in question at the time the patent application was filed. *See Vas-Cath, Inc.*, 935 F.2d at 1562–63. In this regard, we agree with Appellants

it follows that since illumination source 242 is configured to provide light when the device is being used, one of ordinary skill in the art would understand that the disclosure adequately supports simultaneous delivery of nontherapeutic energy (e.g., light) and therapeutic energy (e.g., heat) to tissue at a treatment site of the airway of a lung.

(Reply Br. 5).

In view of the above, we do not sustain the Examiner’s rejection of claim 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Indefiniteness

We are persuaded by Appellants' argument that the Examiner erred in rejecting independent claim 11 and dependent claims claim 12 and 29–38 under 35 U.S.C. § 112, second paragraph (*see* Appeal Br. 10–12).

In rejecting independent claim 11 as indefinite, the Examiner finds it is unclear to the Examiner how if the tissue images are of the portion of the airway of the lung proximate (defined as [1] immediately preceding or following or [2] very near, close) the first treatment site then the tissue images can then display both tissue at the first treatment site and tissue apart from the first treatment site as is currently claimed.

(Final Act. 3 (brackets in original)). The Examiner further notes that because

the Examiner does not believe that the “tissue images of a portion of the airway of the lung proximate the first treatment site” encompass the tissue of the first treatment site, it is unclear to the Examiner how the tissue images would then show both the tissue of the first treatment site and the tissue apart from the first treatment site.

(Ans. 12–13.).

In response, Appellants take the position that the Examiner's rejection is improper because “one skilled in the art would understand what is claimed when the claim terms are given their ordinary and customary meaning” (Appeal Br. 10–11). In this regard, Appellants assert that “an image of tissue ‘proximate’ to a first treatment site should be interpreted as an image of tissue that is ‘very near’ to the first treatment site,” and as such, “[t]he language of claim 11 requires that ‘the tissue images [of a portion of the lung airway proximate the first treatment site] show both tissue at the first treatment site . . . and tissue apart from the first treatment site’” (*id.* at 12 (alterations original)).

The test for indefiniteness under 35 U.S.C. § 112, second paragraph, is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Here, we agree with Appellants that a person of ordinary skill in the art would understand that “the claim requires images of tissue near a first treatment site to be filtered so as to include images showing both treated and untreated tissue, which is clear in light of the disclosure in Appellant’s specification differentiating treated tissue from untreated tissue using filtered images” (Appeal Br. 12 (citing Spec. ¶¶ 25, 108–109)). We also agree with Appellants that “the claim phrase requiring filtering of images of tissue ‘proximate the first treatment site,’ does not necessarily exclude the first treatment site from the filtered images” (*id.*).

In view of the foregoing, we do not sustain the Examiner’s rejection of claims 11, 12, and 29–38 under 35 U.S.C. § 112, second paragraph.

Obviousness

Independent claim 11 and dependent claims 12, 29, and 32–38

We are not persuaded by Appellants’ argument that the Examiner erred in rejecting independent claim 11 under 35 U.S.C. § 103(a) because the combination of Laufer and McGee fails to disclose or suggest limitations [b] and [c] of independent claim 11 which recite

filtering tissue images of a portion of the airway of the lung . . . wherein the tissue images show both tissue at the first treatment site that has received the therapeutic energy . . . and tissue apart from the first treatment site that has not received the therapeutic energy; and determining a second treatment site

along the portion of the airway of the lung based on the filtered tissue images.

(*See* Appeal Br. 13–17; *see also* Reply Br. 6–12). Instead, we agree with the Examiner that the combination of Laufer and McGee discloses the argued limitations (*see* Final Act. 4–6 (citing Laufer, col. 9, ll. 39–47; McGee, col. 8, l. 25 – col. 9, l. 49); *see also* Ans. 13–17).

Laufer is directed “to a device and method for treatment of the airway obstruction found in chronic obstructive pulmonary diseases (COPD), such as cystic fibrosis, chronic bronchitis, emphysema, and asthma” (Laufer, col. 1, ll. 11–15). Laufer discloses

a bronchoscope **430** having a heat treatment apparatus **470** slidably positioned within a lumen. The device also includes an image-transmitting fiber **450** and illuminating fiber **452**. Any conventional bronchoscope with an appropriately sized and directed working lumen may be employed. The image transmitting fiber collects light from the distal end of the treating apparatus and directs the light to a viewing apparatus (not shown) for displaying an image of the obstructed air passage. The bronchoscope may have a panning system which enables the tips to be moved in different directions.

(*Id.* at col. 9, ll. 39–49). Laufer further discloses

[d]epending on the size of the treatment device, the treatment device can be moved to another position for further heat treatment of the air passage. This process can be repeated as many times as necessary to form a series of patency bands supporting an air passage. This procedure is applied to a sufficient number of air passages until the physician determines that he is finished.

(*Id.* at col. 9, ll. 55–62).

McGee “is directed to systems and methods for visualizing interior regions of the human body” (McGee, col. 1, ll. 6–7). McGee discloses an image acquisition element (IAE) which “can comprise an apparatus for

obtaining an image through optical coherence tomography (OCT)” (*id.* at col. 8, ll. 26–29). More particularly, McGee discloses “[a] type of OCT imaging device called an optical coherence domain reflectometer (OCDR)” which “is capable of electronically performing two- and three-dimensional image scans over an extended longitudinal or depth range with sharp focus and high resolution and sensitivity over the range” (*id.* at col. 8, ll. 34–38).

In this regard, McGee discloses

[t]he optical energy supplied to the distal optic path end **220** is transmitted by the lens **228** for reflection by the surface **230** toward tissue T. The scanned tissue T (including anatomic structures, other internal tissue topographic features, and deposits or lesions on the tissue) reflects the optic energy, as will the surrounding support structure **20**. The reflected optic energy returns via the optic path **222** to the optical coupler **240**.

(*Id.* at col. 9, ll. 1–8). McGee further discloses

[r]eflections received from the optical path **222** (from the lens **228**) and the optical path **244** (from the end mirror **250**) are received by the optical coupler **240**. The optical coupler **240** combines the reflected optical signals. Due to movement of the corner-cube retro-reflector **246**, the combined signals have interference fringes for reflections in which the difference in the reflected path lengths is less than the source coherence length. Due to movement of the corner-cube retro-reflector **246**, the combined signals also have an instantaneous modulating frequency.

(*Id.* at col. 9, ll. 30–39). Following, McGee discloses that “[t]he combined output is coupled via fiber optic path **252** to a signal processor **254**. The signal processor **254** converts the optical output of the coupler **240** to voltage-varying electrical signals, which are demodulated and analyzed by a microprocessor to provide an image output to a display device **256**” (*id.* at col. 9, ll. 40–46).

Appellants also argue that Laufer fails to disclose or suggest “filtering images of tissue that include both treated and untreated tissue, much less determining a second treatment site based on filtered images of treated and untreated tissue” (Appeal Br. 13–14; *see also* Reply Br. 6–9). However, Appellants’ argument is not persuasive at least because independent claim 11 is rejected as unpatentable over the combination of Laufer and McGee, and not over Laufer alone. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“Non-obviousness cannot be established by attacking the references individually where the rejection is based upon the teachings of a combination of references.”). Here, the Examiner relies on Laufer to the extent Laufer discloses

displaying tissue images of a portion of the airway of the lung . . . wherein the tissue images show both tissue at the first treatment site that has received the therapeutic energy . . . and tissue apart from the first treatment site that has not received the therapeutic energy . . . so as to differentiate treated tissue from untreated tissue.

(Final Act. 5 (citing Laufer, col. 9, ll. 39–47)). In this regard, the Examiner takes the position that Laufer’s “bronchoscope functions via an image transmitting fiber to provide the displaying of images of the airway to be viewed by a user” (Ans. 14). The Examiner also relies on Laufer as disclosing “determining a second treatment site along the portion of the airway of the lung based on the tissue images” (Final Act. 5 (citing Laufer, col. 9, ll. 39–47), but acknowledges that “Laufer fails to specifically recite that the tissue images are filtered with the determining being based on the filtering and that such filtering is electronic” (Final Act. 5). And, to address these deficiencies, the Examiner turns to McGee (*id.*). More particularly, the Examiner relies on McGee as disclosing

a similar expandable device as that of Laufer which includes a visualization system for assessing areas which need treatment as well as areas which have been treated. McGee further discloses with respect to the embodiment in figure 25, the use of optical coherence tomography (OCT) utilizing a fiber path to provide for a[n] image with sharp focus and high resolution (see col. 8; 25–61). McGee further discloses the function of such an OCT system wherein the tissue images are processed/analyzed/filtered by the system including an electronic signal processor (254) to produce an image output for the user to view (see col. 8, 25 – col. 9; 49).

(*Id.* at 5–6). Thus, Appellants’ argument regarding Laufer alone is not persuasive to show error in the Examiner’s rejection.

Appellants further argue that “McGee fails to teach the filtering of images, much less determining a second treatment site based on filtered images of treated and untreated tissue” (Appeal Br. 16; *see also* Reply Br. 10–12). Again, however, Appellants’ argument is not persuasive at least because independent claim 11 is rejected as unpatentable over the combination of Laufer and McGee, and not over McGee alone. *See Merck*, 800 F.2d at 1097. Here, the Examiner takes the position, and we agree

that McGee does indeed require the filtering of images acquired by the OCT system when the image output is demodulated. It then follows that, in order to obtain the tissue images of the of the [sic] airway as discussed in Laufer utilizing that OCT system of McGee, the displaying of the tissue images for observation by the user would include the step of filtering the tissue images via the demodulation of the tissue images. Given that the tissue images in the combined system of Laufer and McGee are filtered for the observation by the user, the subsequent determination of a second treatment site (the repeating of the treatment at other sites by the energy delivery device in col. 9; 58–60 of McGee) would then be determined or “based” off these “filtered tissue images”.

(Ans. 16). Thus, Appellants' argument regarding McGee alone is not persuasive to show error in the Examiner's rejection.

We also are not persuaded by Appellants' argument that the Examiner erred in rejecting independent claim 11 under 35 U.S.C. § 103(a) because McGee, on which the Examiner relies, fails to disclose or suggest "a filtering step," as required by limitation [b], because McGee merely "teaches OCT image processing that includes sharp focus, high resolution images, as well as the teaching of demodulated and analyzed image output" (Appeal Br. 16–17; *see also* Reply Br. 9–12). Instead, we agree with the Examiner that McGee's disclosure regarding demodulation (*see* McGee, col. 8, ll. 26–38; col. 9, ll. 30–45) corresponds to the claimed "filtering" of images, as required by independent claim 11. We note this interpretation is reasonable in light of Appellants' Specification which does not provide any explicit definition of "filtering" but discloses generally that

digital (electronic) filtering of the image from CCD chip mounted at the end of the bronchoscope may permit filtering for desirable wavelengths and/or the image could be amplified to enable discernment. In addition, so long as long [sic] the system delivers light containing a broad spectrum of wavelengths, electronic or manual filtering may allow for filtering out any undesirable components.

(Spec. ¶ 110).

In view of the foregoing, we sustain the Examiner's rejection of independent claim 11 under 35 U.S.C. § 103(a). For the same reasons, we also sustain the Examiner's rejection of claims 12, 29, and 32–38, which were not separately argued.

Dependent claims 30 and 31

Appellants do not present any additional arguments in support of the patentability of claims 30 and 31 (*see* Appeal Br. 17; *see also* Reply Br. 12).

We are not persuaded, for the reasons outlined above, that the Examiner erred in rejecting independent claim 11 under 35 U.S.C. § 103(a). Therefore, we sustain the Examiner's rejection of claims 30 and 31 under 35 U.S.C. § 103(a) for the same reasons.

DECISION

The Examiner's rejection of claim 33 under 35 U.S.C. § 112, first paragraph, is reversed.

The Examiner's rejection of claims 11, 12, and 29–38 under 35 U.S.C. § 112, second paragraph, is reversed.

The Examiner's rejections of claims 11, 12, and 29–38 under 35 U.S.C. § 103(a) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED